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TITLE: Demonstrating the Efficacy of Group Prolonged Exposure Treatment of PTSD in OEF/OIF/OND Male Veterans

PRINCIPAL INVESTIGATOR: K. Janet C'de Baca

CONTRACTING ORGANIZATION: Biomedical Research Institute of New Mexico
Albuquerque, NM 87108

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6. AUTHOR(S)
Janet Kathreen C'de Baca

E-Mail: Kathreen.CdeBaca@va.gov

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Biomedical Research Institute of New Mexico
1501 San Pedro Drive SE; Bldg. 14 (151)
Albuquerque, NM 87108

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This study will establish the efficacy of delivering prolonged exposure for the treatment of PTSD in a group format. The study population is male OEF/OIF/OND veterans who will be block randomized in groups of 3 into a 10-week, 90-minute, Prolonged Exposure Group (PEG) or Present-Centered Therapy (PCT) group. The goal of the PEG therapy is to promote emotional processing of the trauma memory and desensitize anxiety reactions to trauma memories, so that memories or situations no longer result in anxious arousal to trauma followed by escape or avoidance behaviors. PCT is a non-trauma focused treatment for PTSD, where the mechanisms of change include altering current maladaptive relational patterns and behaviors, providing psycho-education regarding the relationship between trauma and current relational patterns and behaviors, and teaching the use of problem solving strategies to address present life problems. Hypothesis 1. The Prolonged Exposure Group treatment will significantly lower PTSD symptoms compared to the Present-Centered Therapy control group. Hypothesis 2. While subjects in both groups will improve in self-reported overall PTSD symptomatology, the PEG will show greater within group improvement compared to the PCT group. Hypothesis 3. Perceived stigma associated with having a PTSD diagnosis and seeking treatment will significantly decrease for subjects in the PEG compared with subjects in the PCT group.

15. SUBJECT TERMS
PTSD, Group Treatment, Male Veterans, OEF/OIF/OND

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. **INTRODUCTION:** The efficacy of exposure therapy has been established when delivered in an individual format. This study will establish the efficacy of delivering prolonged exposure for the treatment of PTSD in a group format. We will recruit and assess 376 male OEF/OIF/OND veterans, and with an estimated 20% dropout rate, 300 subjects will be block randomized in groups of 3 into a 10-week, 90-minute, Prolonged Exposure Group (PEG) or Present-Centered Therapy (PCT) group. The goal of the PEG therapy is to promote emotional processing of the trauma memory and desensitize anxiety reactions to trauma memories, so that memories or situations no longer result in anxious arousal to trauma followed by escape or avoidance behaviors. PCT is a non-trauma focused treatment for PTSD, where the mechanisms of change include altering current maladaptive relational patterns and behaviors, providing psycho-education regarding the relationship between trauma and current relational patterns and behaviors, and teaching the use of problem solving strategies to address present life problems. Hypothesis 1: The Prolonged Exposure Group treatment will significantly lower PTSD symptoms compared to the Present-Centered Therapy control group. Hypothesis 2: While subjects in both groups will improve in self-reported overall PTSD symptomatology, the PEG will show greater within group improvement compared to the PCT group. Hypothesis 3: Perceived stigma associated with having a PTSD diagnosis and seeking treatment will significantly decrease for subjects in the PEG compared with subjects in the PCT group.

2. **KEYWORDS:** PTSD, Group Treatment, Male Veterans, OEF/OIF/OND.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

Major Task 1: Adapt the Prolonged Exposure (PE) protocol to be delivered in a group format (months 1 through 6).

Major Task 2: Recruiting, Hiring, and Training Study Staff, and Securing Space Allocation for New Staff (months 1 through 6).

Major Task 3: Subject Recruitment, Baseline Assessment, and Randomization (months 7 through 33).

Major Task 4: Post-Treatment, 3– and 6-Month Follow-up Assessments (months 6 through 39)

Major Task 5: Data Entry (weekly), Reliability (quarterly) and Fidelity Checks (yearly)

Major Task 6: Disseminating Findings at Professional Conference Presentations, and through Abstracts, Publications, and DoD (months 33 through 48)

a. What was accomplished under these goals?

Major Task 1

1. Adapted individual Prolonged Exposure protocol for group delivery
2. Prepared Regulatory Documents and Research Protocol
3. Refined eligibility criteria, exclusion criteria, screening protocol
4. Finalized consent form and human subjects protocol

5. Completed and submitted IRB paperwork
6. Obtained IRB approval on 01/13/2015
7. Obtained R&D approval on 03/31/2015
8. Finalized assessment measurements and obtained instruments
9. Submitted amendments as needed, approval on 09/09/2015
10. Obtained DoD approval on 09/28/2015

Major Task 2

1. Developed job descriptions
2. Advertised and interviewed potential staff
3. Selected staff, offered positions
4. Secured offices for new staff
5. Hired Psych Tech, RA, Therapists by 08/2015
6. Standardized training of staff on study protocol:
   - Therapists: Prolonged Exposure and Present-Centered Therapy protocols
   - Psych Tech/RA: Assessment Instruments, Motivational techniques, database development/management
7. Developed database and data entry screens

Major Task 3

1. Present study to NMVAHCS Men's PTSD clinic staff, provide brochures/flyers
2. Present study to NMVAHCS OEF/OIF/OND Coordinator, provide brochures/flyers
3. Contact CBOCs and Vet Center to present study to clinic staff, provide brochures/flyers

Goals not met:

Several potential Psychologists/Study Coordinators applied, and some were qualified and interviewed; offers were made to four applicants over the past year, however, the position remained open. The most frequently cited reason was the desire to obtain a permanent position within the VA system. The position for the Psychologist/Study Coordinator has recently been accepted by a well-qualified applicant, and this person is going through the hiring process now.

Recruitment could not begin until DoD and IRB approvals were obtained. The DoD approval was on 09/28/2015, and we began recruitment efforts there afterward.

b. What opportunities for training and professional development has the project provided?

1. All study personnel have been trained in-house on the study protocol.
2. The therapist who will be conducting the group Prolonged Exposure was trained by Dr Diane Castillo, and is working toward certification.
3. The group Present-Centered Therapy protocol was modified for this study in consultation with Dr Tracie Shea, and included the study therapist.
4. The Psych Tech and Research Assistant and other study staff attended CAPS-5 training conducted by Dr Frank Weathers.

c. How were the results disseminated to communities of interest?

Nothing to Report

d. What do you plan to do during the next reporting period to accomplish the goals?

The next reporting period will focus on recruitment:

Subject Recruitment, Baseline Assessments, and Randomization

Post-Treatment, 3– and 6-Month Follow-up Assessments

Data Entry, Reliability and Fidelity Checks

4. IMPACT:

a. What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

b. What was the impact on other disciplines?

Nothing to Report

c. What was the impact on technology transfer?

Nothing to Report

d. What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

a. Changes in approach and reasons for change

Nothing to Report

b. Actual or anticipated problems or delays and actions or plans to resolve them

The problem of hiring a Study Coordinator has been resolved, and Dr. Tim Ozechowski has been hired.

The delay in recruitment is resolved, and we are currently actively recruiting subjects.

c. Changes that had a significant impact on expenditures

Nothing to Report

d. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report

e. Significant changes in use or care of human subjects

Nothing to Report

f. Significant changes in use or care of vertebrate animals. N/A

g. Significant changes in use of biohazards and/or select agents. N/A

6. PRODUCTS: N/A

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

a. What individuals have worked on the project?

Name:	K. Janet C' de Baca
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4.8
Contribution to Project:	The PI is responsible for the administration and coordination of the grant and supervision of all study personnel; supervising the recruitment, testing, and treatment of all study participants, and ensuring the test and treatment data/results are reasonable, entered correctly, and managed appropriately to ensure accuracy and to protect patient confidentiality; and assuring the analysis of the data is performed with integrity, and preparing results for presentation and publication in peer-reviewed journals.
Funding Support:	

Name:	Diane Castillo
Project Role:	Co-PI
Researcher Identifier (e.g.	

ORCID ID):	
Nearest person month worked:	0.60
Contribution to Project:	The Co-PI will be able to step-in as needed for the PI in administering the grant and supervision of study personnel, and will assist in the preparation of results for presentation and publication.
Funding Support:	

Name:	Catherine Hearne
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.60
Contribution to Project:	The Co-Investigator, who is the OEF/OIF/OND point-of-contact and works primarily with recently returned Veterans, facilitating transition with the OEF/OIF/OND team will work with the research team to facilitate integration of the proposed project into her clinic, develop effective referral procedures, participate in resolving obstacles to recruitment, and participate in data analysis and manuscript preparation.
Funding Support:	

Name:	Christine Chee
Project Role:	Research Monitor
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.60
Contribution to Project:	The Research Monitor is responsible to oversee the safety of the research and report observations/findings to the NMVAHCS IRB or a designated official, and will review all unanticipated problems involving risks to subjects or others associated with the protocol and provide an independent report of the event to the NMVAHCS IRB.

	The Research Monitor may discuss the research protocol with the investigators, shall have authority to stop the research protocol in progress, remove individual human subjects from the study, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and shall have the responsibility to promptly report their observations and findings to the NMVAHCS IRB or other designated official and the HRPO.
Funding Support:	

Name:	Jenna Keller
Project Role:	Psychology Technician
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12.0
Contribution to Project:	The Psychology Technician is responsible for performing assessments on study subjects (baseline, post-treatment, 3- and 6-month follow-up assessments); administering self-report instruments; and assisting with recruitment, scheduling, and data entry as needed.
Funding Support:	

Name:	Nichole Mays
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12.00
Contribution to Project:	The Research Assistant is responsible for assisting with assessments, scheduling and tracking post-treatment, 3- and 6-month follow-up assessments in a timely manner to assure study guidelines; and entering data accurately; and assisting with the recruitment of subjects.

Funding Support:	

Name:	Elizabeth McCallion
Project Role:	Therapist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6.00
Contribution to Project:	This Master's level clinician has been trained in the group Prolonged Exposure therapy and will be responsible for conducting 50, 3-person, 90-minute, 10-session group Prolonged Exposure therapy sessions over a 33 month period; and for maintaining subject treatment files, administering/scoring PCL-5's, monitoring session audiorecordings by subjects, providing handouts, and videotaping sessions for fidelity checks.
Funding Support:	

Name:	Elizabeth McLaughlin
Project Role:	Therapist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6.00
Contribution to Project:	This Master's level clinician has been trained in the group Present-Centered Therapy protocol and will be responsible for conducting 50, 3-person, 90-minute, 10-session Present-Centered Therapy groups over a 33 month period; and for maintaining subject treatment files, administering/scoring PCL-5's, providing handouts, and videotaping sessions for fidelity checks.
Funding Support:	

b. Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

c. What other organizations were involved as partners? N/A

8. SPECIAL REPORTING REQUIREMENTS N/A

9. APPENDICES: N/A

DO NOT RENUMBER PAGES IN THE APPENDICES.